

**Comments of ENCA European Network of Childbirth Associations
to the working document on the draft
Commission Directive on Infant formulae and Follow-on Formulae
SANCO D4/HL/mm/D440180 rev 2 of February 2005**

Our most important comments are in

Whereas (2) and article1,
Whereas (4),
Article 2(d)
Article 7.7 and 8.2(f)
Article 8.7.
Article 9 entirely

Detailed comments

Whereas (2)

A definition of good health should be included in Art 2. If this is impossible to define than delete “good health” here and throughout the text

Rationale: There are a lot of formulas directed to certain conditions as spitting, sleep disorders, colic and.... Are these babies in good health?? or do these babies need special medical formulae. These formulae should come under this directive.

Whereas(3) and Whereas(3) bis1

Delete:” if necessary” and “when necessary”

This creates new loopholes, because no body is assigned to decide what is necessary nor does guidelines exist.

Whereas(4)

As Codex Alimentarius is currently bringing all infant formulas including those for special medical purposes under one standard with two parts, why is the commission not following this way?

Whereas (6)

Delete last sentence.

Rationale: Following the recent outcome of the discussion in the Joint FAO/ WHO workshop on Enterobacter Sakazakii, the discussion in the Codex Committee for Food Hygiene and the EFSA opinion related to microbiological risks in infant formulae and follow-on formulae, drafting should start immediately. If it could not come to a final conclusion before the finalisation of the recast directive than meanwhile adequate warnings on the labels and in every publication on formula feeding should inform care-givers in order to reduce the risk babies are exposed. This is a place to apply precaution up to a final scientific outcome (see whereas (9))

Whereas (19)

Only delete “four to” and keep “six” in the text

Rationale: the text as it reads in the draft can lead to confusions and to too early or too late introduction of complementary feeding

Last line: "during the period" needs to be defined to read "the first six months" to be consistent with 2nd line of same para and what was just said.

Whereas (23)

Further restrictions are needed as the past has shown that claims are used as a marketing tool and undermine breastfeeding. See comments to article 8.7

Whereas (24)

Since the 34th WHA a whole range of WHA resolutions on infant feeding have been accepted with the voices of the EU MS. They have the same legal status as the International code and should therefore be included here and taken into consideration in the text as appropriate.

Whereas (25)

To reflect gender issues adequately change to read "by parents to be and parents of infants"

Whereas (28)

Products intended for export to third countries should follow the same criteria as those for the internal market.

Article 1

See whereas (2) related to good health

Article 2(c)

Only delete "four to" and keep "six" in the text to give clear information and to prevent too early or too late introduction of appropriate complementary feeding.

Article 2(c) and 2(d)

Replace "foodstuffs" by "breastmilk substitute" as this is what they are

Rationale for 2(d): as breastfeeding can go on with adequate complementary feeding as advised in the global strategy on infant and young child feeding, any liquid introduced is replacing breastfeeding.

The view reported by the SCF at page 14 of their report "infant formulae may also continue to be used during the later part of infancy as part of a progressively diversified diet" should be reflected somewhere in the definitions and on the label of infant formula.

Article 2(f)

Define "infants in good health", terms used without definition in whereas (2) and article 1

Article 3

Insert between first months "six" to read the "first six months of life".

Article 4

1. Introduce in the 3rd line "peer-reviewed" between "generally accepted scientific data" to read "generally accepted peer-reviewed scientific data" If EFSA is doing this review then it should be named here if it is another body than it should be named for sake of transparency.

2. What is with ingredients already on the market now in limited products, as for example, pre- and probiotics, but where the scientific evidence to use them with infants is not yet unanimous? Are they going to be reviewed?

2. second last line: Introduce “that is peer-reviewed and published in recognized journals” after “scientific work” to read: “scientific work that is peer-reviewed and published in recognized journals and the data.....”

4. same insert as in 4.1.in first line on page 8: Introduce “peer-reviewed” between generally accepted scientific data to read “accepted peer-reviewed scientific data” If EFSA is doing this review than it should be named here if it is another body than it should be named for seek of transparency.

We feel that the introduction of new or modified product by only sending a copy of the label to the relevant national authorities is not enough to protect the health of babies fed on breastmilk substitutes. This is in contrast to the requirements expressed by the scientific community worldwide, such as expressed in the SCF report, in the LSRO report and the report of an ESPGHAN sponsored workshop on these issues as well as the US FDA. All unanimously agree that any significant modifications of formulae for infants need to be closely reviewed and evaluated with regard to their suitability and safety for the infants for whom they are intended by an independent scientific panel PRIOR to the introduction into the market. Introducing modifications without having them reviewed by competent bodies seems irresponsible and looks like uncontrolled field testing on human babies, given the major impact that details of formula properties may have on infant health.

Article 5.

The water to be added should be defined in order that it is clear if it should be drinking water boiled before use.

Article 7.7

There is a necessity to establish criteria.

Rationale: Following the recent outcome of the discussion in the Joint FAO/ WHO workshop on Enterobacter Sakazakii, the discussion in the Codex Committee for Food Hygiene and the EFSA opinion related to microbiological risks in infant formulae and follow-on formulae, drafting should start immediately. If it could not come to a final conclusion before the finalisation of the recast directive than meanwhile adequate warnings on the labels and in every publication on formula feeding should inform care-givers in order to reduce the risk babies are exposed. This is a place to apply precaution up to a final scientific outcome (see whereas (9))

Article 8.1

Why not follow the example of the Nordic countries where the product name reflects clearly that it is a replacement for breast milk

Article 8.2(f)

Elaborate this warning more to reflect the recent outcome of the discussion in the Joint FAO/ WHO workshop on Enterobacter Sakazakii, the discussion in the Codex Committee for Food Hygiene and the EFSA opinion related to microbiological risks in infant formulae and follow-on formulae. See comments to article 7.7

Article 8.5(a) and (b)

Considering the actual practice of having it in a small place a font size and a percentage of the labelling space used for this important notice should be defined

8.5a and b, 8.6 add follow on formula to these labelling in order to guarantee that partial breastfeeding along with complementary food is protected for as long as recommended in the global strategy

Article 8.7

Considering the misuse of health and nutrition claims to market the products and to undermine breastfeeding further restrictions are needed. In order to be consistent with article 1 and the last sentence in article 9(1) and Whereas (20), (24) and (25) allowing no claims for infant formulae and follow-on formulae is the only adequate solution.

Article 9

Delete “publications specialising in baby care” as this is interpreted differently in different MS and this opens the door to target parents. Keeping this is contrary to the provisions of the international Code (article 5.1). The advertising in scientific publications must be scientific and factual as defined in the International Code

Article 9.1., 9.2. and 9.3.

Add to read in 9.1 and 9.2.: “of infant formulae **and follow-on formulae ...**” and add to read in 9.3: “Manufacturers and distributors of infant formulae **and follow-on formulae ...**” to protect continued breastfeeding in consistence with article 8.4 and the provisions of the International Code (article 5.1).

Article 10.2

Change “mothers” to “parents” to reflect gender issues in sharing responsibilities in child care

Composition

Annex I and II

Review soy as an ingredient

Both the report of the UK Committee on Toxicity (COT) and the report of the Scientific Advisory Committee on Nutrition (SACN) on Phytoestrogens and Health (<http://www.food.gov.uk>), regarding the potential risks of soy as a constituent of infant formula, questioned the safety of the use of soy formula.

The SACN report states:

“Conclusion

20. Based on the evidence cited in the report, SACN is in agreement that the use of soy-based infant formulae is of concern. Whilst there is clear evidence of potential risk, there is no evidence that these products confer any health benefit or therapeutic advantage over products based on cow’s milk protein isolates....there are no substantive medical or clinical indications for the use of soy-based formulae and, secondly on grounds of potentially important sequelae, principally amongst young infants. If the use of soy-based formula is to continue on “clinical” grounds, responsibility is placed upon health professionals rather than the industry and consumers.

The SCF is of the opinion that soy-based formula should be reserved for specific situations only and that cows’ milk based formula should be the standard choice

Annex IV

No longer necessary see comments made to article 8.7

Further rationale: during the existence of this annex no independent scientific evidence has been conclusive on the claims made.

This view is supported by the report of the SCF p 48 “it has been shown for some products that they were nutritionally inadequate. It is unknown if such products were removed from the market. The inherent claim that hydrolysates result in less allergic diseases cannot be deduced

from technical data alone and needs substantiation in clinical trials. Surprising is the total lack of clinical studies published on follow-on formulae based on partially hydrolysed proteins.”

And pages 50 + 51 of the SCF report: “To our knowledge there are no systematic studies to assess growth and biological parameters of infant formulae with partially hydrolysed protein to determine the minimal safe protein content.”

Annex V and VI

We would like to know on which reference the changed values for human milk are based. How could it be certain that this are the “right values” as human milk composition is changing during the feed and there are circadian changes in composition too.

This list doesn’t consider the compositional changes in human milk during a feed, related to circadian changes or changes occurring during the time of breastfeeding to offer a special, unique tailored nutrition to best fit human babies. Any such list and any breastmilk substitute produced in following this list could only have an approximate nutritional composition compared to breastmilk. This should be highlighted here not to induce confusion.